REMARKS

Applicant respectfully requests entry of the above amendment. Claim 28 is currently amended. No new matter was added with this amendment.

Office Action Rejections

1) Rejection based on 35 USC §112

Claim 28 was rejected for failure to define Formula (1a) within the scope of the independent claim. Applicant has amended the claim accordingly. Therefore, the rejection is deemed moot and Applicant respectfully requests said rejection be withdrawn.

2) Rejection based on 35 USC §103(a)

The Action rejected Claims 11, 13-16, 19, and 29 based on US Patent No. 7,163,681 (Giles-Komar et. al.), WO03/009848 (Bronk, et.al.), and further in view of Ono et.al. Eur J. Pharm Sci., 8, p133-139, (1999).

Giles-Komar recites isolated human anti-integrin α-V subunit antibodies, immunoglobulins, and cleavage products, compositions thereof, for the treatment of cell adhesion diseases involving α-V integrin mediated angiogensis. The citation provides a general discussion of literally thousands of potential formulation permutations using excipients and additives disclosed within columns 42-44 and 52-57), including cyclodextrins and antimicrobial agents. According to the citation, "any suitable concentration or mixture" of an antimicrobial agent, can be used in the formulation (column 43, line 46). Further, the citation numerously states that the formulations can be prepared using conventional procedures without providing any guidance relative to the problems associated with cyclodextrin complexation. Examiner has merely looked over the list of hundreds of excipients and highlighted two of which are common with the instant invention. In Pfizer, Inc., v. Apotex, Inc., 480 F.3d 1348 (Fed. Cir, 2007), the court found that an "obvious to try" approach was obvious when a finite number (n=53) of predictable solutions was disclosed. Further, in KSR Intl Co., v. Teleflex Inc., 127 S.Ct. 1727, (2007) recognized that "[w]hen there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to

pursue the known options". More recently, the CAFC in In re Kubin and Goodwin, 2008-1184 , April 2009, the court outlined two classes of situations where "obvious to try" is erroneously equated with obviousness under §103, while referencing In re O'Farrell, 853 F.2d 894, 903 (Fed. Cir. 1988). In the first, what would have been "obvious to try" would have been to vary all parameters or try each of numerous possible choices until one possibly arrived at a successful result, where the prior art gave no indication of which parameters were critical or no direction as to which of many possible choices is likely to be successful. In such circumstances, this equates to "merely throwing metaphorical darts at a board filled with combinatorial prior art possibilities", and succumbing to hindsight of obviousness. Applicant contends that the Giles-Komar citation does not provide a finite number of predictable options for the skilled artisan, particularly since cyclodextrin complexation has been shown to be problematic and unpredictable, and that the Office Action has succumbed to hindsight by merely picking two of the excipients from an enormous pool of options.

Bronk, discloses the use of a compound of Formula (1a) to modify unwanted anxiety behavior in companion animals, i.e., abnormal vocalization, hyperactivity, and others. Bronk only recites a parenteral formulation comprising either sesame or peanut oil in aqueous propylene glycol. There is nothing recited in Bronk (e.g., no predictable variation of formulation excipients) that would lead the skilled artisan to choose specific excipients from Giles-Komar to prepare the formulation of the instant invention. Further, the addition of the complexation issues of cyclodextrin described by Ono (below) would lead the skilled artisan away from using cyclodextrin in a formulation with an active ingredient and second guest molecule (e.g., anti-microbial).

Ono recites complexation issues relative to the use of cyclodextrins, particularly as they relate to the solubility and permeation of phenacetin and various benzoic acids. Phenacetin and the benzoic acid derivatives were employed for modeling complexation because they were known to form 1:1 inclusion complexes with β-cyclodextrins thereby making modeling assumptions simple. Overall, modeling requires the determination of stability- and permeation-rate constants in free and complexed fractions. Per Ono, cyclodextrin complex permeation rates are significantly affected by the presence of second guest molecules because of competitive inclusion. According to the Action, the theoretical 1:1 inclusion complexation binding affinity calculations would be synonymous and/or

obvious with the complexation affinities of a multifaceted formulation, contrary to Ono. Because of the physicochemical and biological properties of a drug, stability constants, permeation rate constants, and competitive inclusion complexation stoichiometry of active drug(s), preservatives, excipients, and cyclodextrins, the skilled artisan would not be able to ascertain the pharmaceutical composition of the instant invention with any predictaability or without undue experimentation.

In light of the aforementioned, Applicant disagrees that it would be obvious for a skilled artisan to prepare the pharmaceutical composition of the instant invention. Overall, the skilled artisan could not have predicted the formulation of the instant invention with any certainty of success in view of Giles-Komar, Bronk, and Ono. Therefore, the rejection is deemed moot and Applicant respectfully requests that the rejection be withdrawn and the claims be allowed to grant.

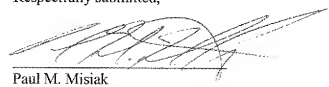
For the aforementioned reasons regarding the composition, claim 29 which depends from claim 11, would be non-obvious.

Conclusion

For the reasons stated above, Applicant respectfully requests that the rejections be withdrawn and the claims as amended be allowed to grant. Applicant believes the application to be in condition for allowance, and respectfully requests an early and favorable action. If needed to progress this application to grant, Applicant invites Examiner to contact Applicant's Attorney, at the number listed below.

Respectfully submitted,

Date: 3-25-2010



Paul M. Misiak
Attorney for Applicants
Reg. No. 58,310

Pfizer Inc.
Patent Department
7000 Portage Rd. KZO-300-106SW
Kalamazoo, MI 49001
(269) 833-4604 (phone)
(269) 833-8897 (facsimile)